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EXAMINER

GAKH. YELENA G

ART UNIT PAPER NUMBER

1743

DATE MAILED: 05/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/806,711

Applicant(s)

MODY, NITA

Examiner

Yelena G. Gakh, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-50 is/are rejected.
- 7) ☒ Claim(s) 3 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Amendment filed 04/04/05 is acknowledged. Claims 1-50 are pending in the application.

#### ***Response to Amendment***

2. The rejections remain essentially the same as were established in the first Office action.

#### ***Claim Objections***

3. Claim 3 is objected to, since the examiner failed to find a support for the language of the claim in the specification. The Applicants are requested to provide an evidence for such support.

#### ***Specification***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to as not containing “a written description of the invention ... in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains ... to make and use the same ... in its best mode”.

It seems that the disclosure is an attempt to cover all possible embodiments involving pH indicators incorporated into single- or multi-layered matrices comprising a variety of materials from non-permeable to superabsorbent, with most of the embodiments well known in the art. Some of the embodiments, e.g. those involving “fluid barrier layers”, which are not permeable to the fluid to be detected, are not enabled, since no fluid can be detected in such layers or can get through these layers to reach another layer with the incorporated pH indicator. The variety of the embodiments covering all possible materials used for detecting or controlling biological fluids or

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moisture by employing pH indicators disclosed in the specification does not allow to clearly and unambiguously identify the essence of the invention and its distinction from the prior art.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not give any guidance of making a pH composite comprising coaxial fibers, the inner layer of which comprises a pH indicator, while the outer layer would control the fluid contact. If such fibers are known, the reference should be provided which enables production of such fibers. If this is an inventive feature of the instant application, a detailed teaching of making such fibers should be provided in the specification. Moreover, the specification does not give any guidance of how such pH composite can be used.

Claims 17, 28 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The specification does not disclose any pH indicator, which provides different responses to the fluid depending on the location of the pH indicator, rather than the concentration of the fluid. The examiner is not aware of such indicators. Additional information on such indicators is required.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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7. Claims 1-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites two layers, one with a fluid-regulating additive to regulate fluid contact with a pH indicator, and second to control fluid contact with said layer. Since both layers are supposed to control fluid contact, i.e. to control fluid flow within the layer, it is not clear, what is the difference between two layers.

In claim 4 it is not clear, what is the difference between the first and second fluid regulating additives.

Claim 7 seems to list regulating additives only for the second layer. It is unclear, therefore, which should be the additives for the first layer.

In claim 12 it is not clear, what is meant by a “threshold amount of fluid” in the environment, and if this amount should be preliminary determined in order to evaluate a moisture vapor transmission rate of the polymer layer?

In claim 13 it is not clear, what is meant by the expression “fibers having surfaces coated with a moisture transmitting component”? What types of “moisture transmitting components” are meant here? It could have been assumed that fibers themselves should transmit moisture.

Claim 16 is indefinite, as it is not clear, if the composite comprises different pH indicators in different locations to give different responses, or it recites something else. The same question arises for claim 18 - are different responses due to the presence of different pH indicators in different locations?

Claims 17, 28 and 41 are not clear as to what is the purpose for having different concentrations of the pH indicator within the thickness, and if these concentrations should be predefined. The response of the pH indicator is not supposed to depend on its concentration; it may affect only a time period for reaching equilibrium upon adding an analyte. Also, the claims recite the limitation “said different responses”, which lacks antecedent basis, since no “different responses” is recited in claim 1.

Claims 26 and 39 are not apparent. It is not clear, how the relation between the extent of penetrating the fluid into the thickness of the matrix and its concentration is established. It is

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also not clear, what is the “concentration” of the fluid in the environment? The concentration is a relative measure. Relative to what the concentration of the fluid is measured?

Claim 35 is not clear as to what the ink layers are, and if the pH indicator is different from ink. If the pH indicator is different from the ink, then what is the role of ink in these ink layers?

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. **Claims 1-2, 4-14, 19-26, 30-39, 41 and 43-50** are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over any of JP 59106501A, Mroz et al. (US 4,231,370, IDS), Zimmer et al. (US 5,089,548, IDS), Mueller (US

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5,167,652), Mitchell et al. (US 5,354,289, IDS), Sasaki et al. (US 5,690,624, IDS), Neadling et al. (US 2001/0049513 A1) and references therein.

The prior art listed above, as well as the prior art recited in the above references discloses a variety of embodiments related to multilayer composites and wetness indicators comprising pH indicators disposed in the layers of the composites with additional layers which control the fluid flow to the layers comprising pH indicators. Diverse materials from non-permeable to superabsorbent are disclosed in the prior art, which are used together with the layers containing pH indicators. In most of the references the transparent window for visual determination of wetness of e.g. diapers is disclosed. The examples and various embodiments are too numerous for specific citations. However, the disclosures are clearly anticipatory or obvious for the pending claims.

### ***Response to Arguments***

12. Applicant's arguments filed 03/11/05 have been fully considered but they are not persuasive.

Regarding the scope of the specification. The specification discloses all possible embodiments of single- and multi-layer wetness indicators comprising layers with pH indicators and "fluid regulating additives", with the additives from the list comprising all possible absorbents, from impermeable to superabsorbent. pH Indicators incorporated in such single and multilayers, which comprise "fluid regulating additives", such as silica gel, superabsorbent polymers, cellulosic resins, anhydrite resins, polyolefin blend resins, calcium oxide, clays and calcium sulfate, are well known in the art, as the multiple references (which is just a selection of the prior art known in the field) disclose. Especially silica gel and superabsorbent polymers are conventional materials used for controlling flow in the wetness indicators. Therefore, it is not clear, what is the specific inventive feature of the present wetness indicators.

Regarding claim 3, the examiner failed to find its support in the specification, as it was indicated above. Moreover, it is not quite clear, what is the role of the barrier recited in claim 3 - to get more liquid before it reaches the indicator? The sense of this embodiment is not clear.

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Regarding coaxial fibers recited in claim 15. The examiner did not question existing or process of making of coaxial fibers. The question was referred to the specific coaxial fibers of the present invention. As the prior art provided by the Applicants themselves teaches, coaxial fibers are usually produced in a high temperature regime when the polymers are melted. The specification does not provide any indication of how it is possible to melt polymers with blended dye or pH indicator within one of them without destroying the indicator. The examiner requested providing any reference for coaxial fibers, with one of their layers (inner or external) carrying a pH indicator, or, if this is a novel feature of the present application, the method of producing such fibers.

Regarding claims 17 and 18. Again, the concentration of pH indicating agent should not affect the response of an analyte. This is the concentration of an analyte, which affects response of the pH indicator. If the response of pH indicators depended on their concentration, it would have never been possible to evaluate the concentration of an analyte. Again, if the Applicants are of a different opinion, the examiner requests any reference from the Applicants, which indicates dependence of the response of pH indicators from their concentration, rather than the concentration of the analyte. Of course, if there is no pH indicator in a specific location, the response will be zero, if this is what the Applicants meant.

Regarding Claim 12, the question of a preliminary evaluation of the threshold value was not answered. If the routineer in the art should preliminary determine such threshold, this has to be reflected in the claim.

Claim 13 is still unclear and indefinite, as no examples of such fibrous layers are given in the specification.

The issues regarding claims 16, 17, 27-29 and 40-42 are not answered.

Regarding rejections over the prior art; JP 59106501A discloses microcapsules comprising pH indicator and fluid regulating additives (e.g. additives dissolved by water or acid or alkaline or wettable such as talc, starch derivatives, etc.) placed on a second layer. US Patent 4,231,370 discloses an extensive prior art, which teaches embodiments with dye incorporated into the layer with regulating additives (talcum powder) (see e.g. US 3,675,654). The patent itself discloses latex composition, comprising polyvinyl acetate, random vinyl acetate-ethylene copolymer (polyolefin blend), etc., which is a fluid controlling material with incorporated dye.



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The comment that the latex is not a fluid-regulating additive is not clear. Other patents either disclose themselves or refer to the prior art, which teaches using superabsorbent polymers, silica gels, talc, etc., as fluid regulating materials, along with pH indicators. The prior art provides a number of embodiments, which disclose pH indicators either incorporated in such materials, or used along with such materials. Again, an unprecedented number of embodiments related to different components, different materials, different locations of different components, etc., disclosed in the present invention, prevents the examiner from addressing each of the embodiments individually. Many of these embodiments do not have a clear interpretation. However, the main idea of having a pH indicator incorporated into a layer having a controlled fluid flow is well known in the art. Moreover, the materials, which would not have such controlled fluid flow, would not be enabled for application in diapers. The only novel feature found by the examiner in the invention is coaxial fibers with one of the layers impregnated with a pH indicator. However, the specification does not provide a sufficient enablement for such fibers.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

5/19/05

  
**YELENA GAKH**  
**PRIMARY EXAMINER**